

F1

19(Twice Amended). The composition according to claim 21, wherein the recombinant AAV further comprises a constitutive promoter.

F2

21(Four Times Amended). A composition comprising a recombinant adeno-associated virus (AAV) suspended in a biologically compatible carrier, wherein said recombinant AAV comprises (a) 5' AAV inverted terminal repeats (ITRs), (b) nucleic acid sequences encoding human apolipoprotein E (ApoE) operably linked to regulatory sequences which direct its expression, and (c) 3' AAV ITRs, and

wherein the recombinant AAV is at least as free of contaminating adenoviral helper virus as is obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation.

22(Amended). The composition according to claim 21, wherein said composition comprises at least 10^9 particles of recombinant AAV.

23(Amended). The composition according to claim 21, wherein the composition comprises 2.5×10^{10} to 5×10^{10} genomes of recombinant AAV.

24(Amended). The composition according to claim 21, wherein the composition comprises 5×10^{10} to 5×10^{11} genomes of recombinant AAV.

26(Amended). A method of delivering apolipoprotein E (ApoE) to a mammal with atherosclerosis, said method comprising the step of

administering to the mammal a composition comprising a recombinant adeno-associated virus (AAV) suspended in a biologically compatible carrier,

wherein said recombinant AAV comprises (a) 5' AAV inverted terminal repeats (ITRs), (b) nucleic acid sequences encoding human apolipoprotein E (ApoE) operably linked to regulatory sequences which direct expression thereof and (c) 3' AAV ITRs, wherein the recombinant AAV is at least as free of contaminating adenoviral helper virus as is obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation,

and wherein the ApoE in said composition is expressed in the mammal.

27(Amended). The method according to claim 26, wherein said recombinant AAV is administered intramuscularly.

28(Amended). The method according to claim 26, wherein said composition comprises at least 10^9 genomes of recombinant AAV.

Kindly add new claims ³⁰~~29~~ to ³⁵~~34~~ as follows.

³⁰~~29~~(New). The method according to claim 26, further comprising the step of monitoring the mammal for expression of ApoE.

³¹
~~30~~(New). A method of delivering apolipoprotein E (ApoE) to a mammal in need of treatment of atherosclerosis, said method comprising the step of administering to the mammal a composition comprising a recombinant adeno-associated virus (AAV) suspended in a biologically compatible carrier intramuscularly,

wherein said recombinant AAV comprises (a) 5' AAV inverted terminal repeats (ITRs), (b) nucleic acid sequences encoding human apolipoprotein E (ApoE) operably linked to regulatory sequences which direct expression thereof and (c) 3' AAV ITRs,

wherein the rAAV is at least as free of contaminating adenoviral helper virus as is obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation

and wherein the ApoE in said composition is expressed in the mammal.

F4 Cont
³²
~~31~~(New). The method according to claim ~~30~~³¹, wherein the composition is administered into the skeletal muscle.

³³
~~32~~(New). The method according to claim ~~30~~³¹, further comprising the step of monitoring the mammal for expression of ApoE.

³⁴
~~33~~(New). The method according to claim ~~30~~³¹, wherein the level of contaminating adenoviral helper virus is the same as that obtained by subjecting said recombinant AAV to four rounds of cesium chloride centrifugation.

³⁵
~~34~~(New). The composition according to claim 21, wherein the level of contaminating adenoviral helper virus is the same as that obtained by subjecting said recombinant AAV to four rounds of cesium chloride centrifugation.